



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stephen J. Brown

Assignee: Health Hero Network

Title: REMOTE HEALTH-MONITORING SYSTEM WITH NETWORKED
SERVER AND HEALTH CARE PROFESSIONAL

Serial No.: 09/237,194 Filed: January 26, 1999

Examiner: Morgan, R. Art Unit: 3626

Attorney Docket No.: 99-0120 / 7553.00029

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF STEPHEN J. BROWN PURSUANT TO 37 C.F.R. S 1.131

I, Stephen J. Brown, hereby declare as follows:

1. I am the sole inventor of the subject matter claimed in the above-identified patent application U.S. Serial Number 09/237,194.
2. The various exhibits that will be referenced in this document relate to the claim elements of the pending claims. In particular, certain documents will relate to the remote patient sites (e.g., patient interface), certain documents will relate to the central server (e.g., database), and certain documents will relate to the health care provider computer (e.g., provider interface). Each of the three main elements had considerable amounts of work in

development that were undertaken. References to the blood glucose meter, and the project Camit EL, the project Nintendo, the project KinderCamit Software, each relate to the patient interface element. Documents relating to Diabcare relate to development of the database element. Documents related to Camit S relate to development of the provider interface. The individual modules were worked on as stand alone elements to develop technologies to be integrated as the system of the present invention. The strategy to integrate the technologies developed through the individual projects was kept confidential.

3. The Nintendo, Diabcare, and Camit S projects were developing modules and system elements that at the time functioned as stand alone products. Diabcare and Camit were modules sold as stand alone systems to Boehringer Mannheim GmbH. The Nintendo projects included diabetes and psychological assessment (attention deficit disorder) modules that were developed in part under Small Business Innovation Research grants from the National Institutes of Health. The diabetes module was sold to Novo Nordisk Pharmaceuticals Inc, Novo Nordisk A/S and to PCSL Software Ireland Ltd. We pursued these projects in order to create technologies and software that we could integrate as a complete modular micro-processor-based health monitoring system, with Nintendo-based patient interface, a network database, and a provider interface for data analysis, as described in my letter of March 2.
4. The above-identified patent application is a continuation of prior U.S. application U.S.S.N. 08/481,925, filed June 7, 1995, now U.S.P.N. 5,899,855, which is a continuation of prior U.S. application U.S.S.N 08/233,397, filed April 26, 1994, now abandoned, which is a

continuation-in-part of prior U.S. application U.S.S.N. 07/977,323, filed November 17, 1992, now U.S.P.N. 5,307,263 (see item 1 on page 1 of the transmittal letter attached as part of Exhibit A and the domestic priority information table on page 2 of the supplemental application data sheet attached as part of Exhibit A).

5. The above-identified patent application claims priority to the filing date (i.e., November 17, 1992) of U.S.P.N. 5,307,263 under 35 U.S.C. §120 (see item 1 on page 1 of the transmittal letter attached as Exhibit A).
6. The effective filing date of U.S. Patent No. 5,390,238 (Kirk et al.) is the date that Kirk et al. is effective as a reference under 35 U.S.C. § 102(e), i.e., June 15, 1992.
7. Prior to June 15, 1992, I conceived the invention claimed in the above-identified patent application as shown by the fax letter from me to Boehringer Mannheim GmbH attached as Exhibit B. The fax letter of Exhibit B shows an original document date of March 2, 1992.
8. The third paragraph of the fax letter attached as Exhibit B describes elements which correspond to those in FIG. 1 of the present patent application. For example, the data management program corresponds to the data management unit 10, the Nintendo video game corresponds to the handheld unit 12, the modem mentioned for connecting a home system to a doctor system corresponds to the modem 52. The statement that the system described in the fax letter could be an ideal platform for a home system which connects to the doctor

system via modem corresponds with the communications with doctors at 52 and the fact that the doctor and patient are remote from each other (implicit in the words “home system which connects to the doctor”).

9. During the period from March 2, 1992 to November 17, 1992, I was the Chief Executive Officer (CEO) of a start-up company, Raya Systems, Inc.
10. During the period from March 2, 1992 to November 17, 1992, I was either diligently working on the present invention, or performing my other duties as CEO of the company. The time line has been detailed with various documents attached as Exhibits C to AB, which are described below.
11. My duties as CEO included preparing applications for grants, which directly contributed to financing needed to develop and produce products related to the present invention, traveling, attending conferences, as well as other items related to the day to day running of the company. As is common for most CEOs, I worked hours far in excess of the normal 40 hour week.
12. On or around March 5, 1992, I indicated to the National Institutes of Health (NIH) that Raya Systems was completing a research plan and intended to prepare an application for Phase II funding (see letter to Dr. Charles Wells attached as pages 1-2 of Exhibit C). The research plan was funded by an NIH grant awarded in response to a grant application I submitted

under the Small Business Innovation and Research (SBIR) program for a project entitled "Computer Game for Diabetes Education" (see grant application and Notice of Award attached as pages 3-7 of Exhibit C). The performance period for the research plan ran from September 5, 1991 through March 5, 1992. After completion of the research plan, I was responsible for writing and submitting a final report on the Diabetes grant.

13. In addition to the Diabetes project, I and others at Raya Systems worked on various interactive patient self-care education and self-monitoring projects supported by Small Business Innovation and Research grants from the National Institutes of Health. I was the principal investigator and dedicated a portion of my time to managing these projects which were related to developing the patient interface for diabetes and several other conditions. One of these conditions was the Attention Deficit Disorder grant, which was a patient interface related project in which we were developing subjective data collection measures from interactive patient software on a Nintendo video game system. I was obligated to spend 25% of my time as principle investigator between March 10, 1992 and September 9, 1992 (see grant application and Notice of Grant Award attached as pages 8-11 of Exhibit C).
14. On or before March 18, 1992, a preliminary design document for KinderCamit was generated as shown by the copy of the design document attached as Exhibit D. The KinderCamit document relates to development of the patient interface portion of the present invention.

15. On March 25, 1992, I received a draft letter to review from Richard Black. A redacted copy of the letter is attached as Exhibit E. The letter concerned negotiations for an exclusive license from video game manufacture Nintendo which was being sought. The license being sought related to the development of the patient interface portion of the present invention.
16. From March 28, 1992 to April 13, 1992, I was involved in preparing the Phase II grant application and soliciting consultants and advisors for the project.
17. On April 13, 1992, the grant application was submitted.
18. A copy of an invoice from Oles, Morrison and Rinker for legal services from March 23, 1992 through April 22, 1992 is attached as Exhibit F. The invoice is dated May 13, 1992 and shows the time spent on March 24, 1992 and on March 25, 1992 in preparation of the letter to Nintendo attached as Exhibit E and, therefore, relates to the development of the patient interface. The invoice also shows that on April 20, 1992, April 21, 1992 and April 22, 1992 I spent time on company business.
19. A fax letter dated May 11, 1992 from Todd Raming to Hartmut Kassulke which includes a time table for development of Camit S 2.5 is attached as Exhibit G. The letter relates to activity pertaining to the development on the provider interface.

20. A copy of a fax, including a Speaker Release Form, from me to Amy Philips dated May 12, 1992 and a letter from Linda Cann to me dated May 4, 1992 is attached as Exhibit H. The fax was sent in preparation for me presenting at the 52nd Annual Scientific Sessions of the American Diabetes Association.
21. A copy of an invoice from Oles, Morrison and Rinker for legal services from April 23, 1992 through May 22, 1992 is attached as Exhibit I. The invoice in Exhibit I is dated June 10, 1992. The invoice shows activity on May 5, 1992, from May 12, 1992 through May 13, 1992, on May 15, 1992, and from May 20, 1992 through May 21, 1992 regarding a contract with Sculptured Software; Inc. The activity related to development of interactive patient self-care education software that would be part of the patient interface portion of the present invention.
22. A copy of a fax letter from me to Hartmut Kassulke dated May 31, 1992 is attached as Exhibit J. The fax includes a letter dated June 1, 1992, which included a status report on the ongoing development of Camit S 2.5 and Diabcare. The letter shows activity related to the database and provider interface portions of the present invention.
23. A copy of a company meeting agenda, dated June 1, 1992, showing employees and projects is attached as Exhibit K. The agenda lists the Nintendo project which was related to the patient interface portion of the present invention.

24. A copy of a fax letter from Jay Clark to me dated June 2, 1992 is attached as Exhibit L. The fax involved an agreement for hiring Jay Clark as a developer. The hiring of Jay Clark related to development of the interactive patient self-care education software that would be part of the patient interface portion of the present invention.
25. A copy of a letter from George Metos, President of Sculptured Software, Incorporated to me dated June 8, 1992 is attached as Exhibit M. The letter concerns employment of a software developer which related to development of interactive patient self-care education software that would be part of the patient interface portion of the present invention.
26. A redacted copy of a letter from me to Dr. Norbert Jersch dated June 16, 1992, is attached as Exhibit N. The letter included a status report concerning the Diabcare project which was related to activity in the development of the database portion of the present invention.
27. A copy of a letter from me to Dr. Klaus Piwernetz dated June 18, 1992, is attached as Exhibit O. The letter relates to activity on the Diabcare project which was related to activity in the development of the database portion of the present invention.
28. A copy of an invoice from Oles, Morrison and Rinker for legal services provided from May 26, 1992 through June 22, 1992 is attached as Exhibit P. The invoice is dated July 28, 1992 and shows time spent on developer contracts, contracts with Nintendo and confidentiality

agreements which relate to development of the patient interface portion of the present invention.

29. A letter to me from Jeffrey P. Brunner of Emerson Brooks and Associates dated June 25, 1992, a redacted copy of a payroll register for June 1992 and a redacted copy of an employee master information payroll record for 1992 are attached as Exhibit Q. Pay amounts and personal identification numbers have been redacted to preserve the privacy of the employee information. The letter to Jeffrey P. Brunner shows that the company agreed to pay Emerson Brooks for the recruitment of Jack Thornton as software development manager. Jack Thornton was hired as Director of Product Development in June 1992. His work included working on the specifications for the present invention. The payroll register (page 4 of 5) shows Jack Thornton was payed as a full time employee during June of 1992. The employee master information payroll record (page 5 of 5) shows Jack Thornton was payed as a full time employee during June through December 1992. The payroll amounts for Jack Thornton contained in (i) the payroll register (page 4 of 5 of Exhibit Q) and (ii) the employee master information payroll record (page 5 of 5 of Exhibit Q), which are redacted, showed that the same amount was payed for each of the months June through December.
30. A copy of a fax of building plans dated June 25, 1992 and a fax letter from Ed Iglesias of Hansen Bros. to Raya Systems dated July 7, 1992 are attached as Exhibit R. The building plans and letter concern moving plans for Raya Systems with which I was involved. The move took place over a period from about mid July, 1992 through about mid August, 1992.

31. On or around July 1, 1992, I traveled to Dublin, Ireland to meet with PCSL Software Ireland LTD, a company with which Raya Systems was doing business and which was interested in funding a series of patient education programs.
32. Copies of letters from Liz Becker of Novo Nordisk A/S to me, dated July 2, 1992 and July 10, 1992, and a letter from me to Liz Becker dated July 14, 1992 are attached as Exhibit S. The letters attached as Exhibit S show discussion and preparation for me, as CEO of Raya Systems, to attend an EASD conference. Although I was unable to attend the EASD conference, I traveled to Copenhagen, Denmark for a meeting with Novo Nordisk A/S, a company with which Raya Systems was doing business, on or around August 21, 1992.
33. On August 7-8, 1992, I was at my sister's wedding in Wenatchee, Washington.
34. From August 10-15, 1992, I was at a family reunion in Deer Valley Ranch, Colorado.
35. On or before August 13, 1992 enough design work had been done to produce a schematic, a list of features, a hardware wish list and a basic hardware design for the present invention, as well as to hire a hardware engineer, Craig Nelson, as a consultant to implement the invention (see the schematic, list of features, hardware wish list, hand-written notes, hardware description and non disclosure agreement of Craig Nelson attached as Exhibit T).

36. All of the documents in Exhibit T were sent on August 14, 1992 to Richard Black at the law firm of Oles, Morrison & Rinker for the preparation of the patent application filed November 17, 1992 (see the copy of Jack Thornton's fax cover sheet and accompanying documents that were sent to Richard Black attached as Exhibit U).
37. A copy of handwritten notes from me to Jack Thornton dated August 21, 1992 are attached as Exhibit V. The notes were faxed from Copenhagen where I was meeting with Novo Nordisk. The notes relate to continuing development of the present invention.
38. By September 3, 1992 attorney Jim Anable had been instructed to prepare the above-identified patent application (see Richard Black's letter dated September 3, 1992 attached as page 1 of Exhibit W).
39. On September 9, 1992, the NIH indicated that our Phase II proposal was being reviewed and requested further information. A copy of the letter from the NIH requesting further information is attached as pages 1-3 of Exhibit X.
40. From September 11, 1992 through September 16, 1992, we worked on responding to the NIH requests for more information regarding our Phase II grant application. A copy of the letter from me to the NIH responding to the request for further information is attached as pages 4-6 of Exhibit X.

41. A retainer was paid to attorney Jim Anable's firm, Christensen O'Conner, et al., on or around September 15, 1992 (see copy of letter and check attached as pages 2-3 of Exhibit W).
42. On September 30, 1992, the NIH issued a Notice of Grant Award and the performance period began for our Phase II project. A copy of the Notice of Grant Award from the NIH is attached as pages 7-10 of Exhibit X.
43. Attorney Anable sent a first draft of the above-identified patent application to me for review on October 2, 1992 (a copy of the fax cover sheet, pages 1 to 28 of the draft application and the set of figures which were provided to me are attached as Exhibit Y).
44. On October 2, 1992, I faxed, to Jim Anable, a drawing to be included in the application. A copy of the fax cover sheet and the drawing are attached as Exhibit Z.
45. From October 2, 1992 to November 17, 1992, Christensen O'Conner et al. continued to work on the application until the filing of the application on November 17, 1992 (see Christensen O'Conner et al. billing statements dated October 31, 1992 and November 30, 1992 attached as Exhibit AA).
46. The patent application to which the present application claims priority was filed in the United States Patent and Trademark Office on November 17, 1992 as indicated by the Filing Date shown on the Official Filing Receipt attached as Exhibit AB.

47. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patents issued therefrom.

Date: September, 19, 2006

A handwritten signature in black ink, appearing to read 'SJB', is written over a horizontal line.

Stephen J. Brown

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